

§ 17.18

party opposing the motion may not rest on mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of material fact for the hearing.

(d) If, on motion under this section, a summary decision is not rendered on all issues or for all the relief asked, and if additional facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings on facts still at issue. The facts specified not to be at issue shall be deemed established.

(e) Except as provided in §17.18, a party may not obtain interlocutory review by the entity deciding the appeal (currently the DAB) of a partial summary decision of the presiding officer. A review of final summary decisions on all issues may be had through the procedure set forth in §17.47.

§ 17.18 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section, rulings of the presiding officer may not be appealed before consideration on appeal of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the entity deciding the appeal (currently the DAB) if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) When an interlocutory appeal is made, a participant may file a brief on the appeal only if specifically authorized by the presiding officer or the entity deciding the appeal (currently the DAB), and if such authorization is granted, only within the period allowed by the presiding officer or the entity deciding the appeal. If a participant is authorized to file a brief, any other participant may file a brief in opposition, within the period allowed by the entity deciding the appeal (currently the DAB). The deadline for filing an interlocutory appeal is subject to the discretion of the presiding officer.

21 CFR Ch. I (4–1–15 Edition)

§ 17.19 Authority of the presiding officer.

(a) The presiding officer shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(b) The presiding officer has the authority to:

(1) Set and change the date, time, and place of the hearing on reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable time;

(3) Require parties to attend conferences for settlement, to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of discovery consistent with §17.23;

(8) Regulate the course of the hearing and the conduct of the parties;

(9) Examine witnesses;

(10) Upon motion of a party for good cause shown, the presiding officer may allow a witness to be recalled for additional testimony;

(11) Receive, rule on, exclude, or limit evidence;

(12) Upon motion of a party or on the presiding officer's own motion, take official notice of facts;

(13) Upon motion of a party, decide cases, in whole or in part, by summary decision when there is no genuine issue of material fact;

(14) Conduct any conference, argument, or hearing on motions in person or by telephone;

(15) Consolidate related or similar proceedings or sever unrelated matters;

(16) Limit the length of pleadings;

(17) Waive, suspend, or modify any rule in this part if the presiding officer determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law;

(18) Issue protective orders pursuant to §17.28; and